SURGICAL FASTENERS AND DEVICES FOR SURGICAL FASTENING

FIELD OF THE INVENTION

This invention relates to surgical fasteners and to surgical fastening devices.

BACKGROUND OF THE INVENTION

Surgical fasteners are used instead of surgical suturing, which is often both time consuming and inconvenient, in order to join two tissue locations. A surgeon can often use a stapling apparatus to implant a fastener into a body tissue and thus accomplish in a few seconds, what would take a much longer time to suture. A surgical fastener is used, for example in inguinal hernia surgery to fasten polypropylene mesh to the abdominal wall in order to reinforce the abdominal wall.

Conventional surgical fasteners have been in the form of ordinary metal staples, which are bent by the delivery apparatus to join together body tissues. These staples comprise a pair of legs or prongs joined together at one end by a crown that may be straight or arcuate.

At present, there are a variety of surgical fasteners and fastening devices available for endoscopic or open procedures, to attach tissues together, or to attach a mesh patch to a tissue. One such surgical fastener is a surgical stapler, or clip applicator. In this stapler, a plurality or stack of unformed staples are contained within a cartridge and are sequentially advanced or fed within the instrument by a spring mechanism. A secondary feeding mechanism is employed to separate the distal most staple from the stack, and to feed the distal most

stapler into the staple closing mechanism. Such mechanisms are found in US Patent Nos. 5,470,010, and 5,582,616.

In some applications, the body tissue is accessible from two opposite direction so that an anvil may be used to deform the legs of a staple after having passed through the body tissue. In applications where access to the tissue is from only one direction, an anvil may be used to deform the crown of a conventional staple so that the legs project towards each other in the body tissue so as to hold the staple in the tissue.

Another stapler mechanism, used mostly for mesh attachment to tissue does not use an anvil. Instead, a fastener comprising a helical wire is screwed or rotated into a tissue, in order to join tissues to affix a polypropylene or similar material mesh or other patch to the tissue together. Instruments and fasteners of this type are found in US Patent Nos. 5,582,616, US 5,810,882, and US 5,830,221. Another type of fastener that does not need an anvil applies fasteners made from a shape memory alloy such as Nitinol^{T}. These fasteners are mainly used to fasten prosthetic material or artificial mesh to tissue.

In the above instruments, a mechanism is used that is located in a slender shaft of the instrument to push the stack of staples or anchors to the distal end of the shaft as the staples are ejected from the distal end. This mechanism prevents the shaft diameter from being reduced below a minimal diameter required to contain the mechanism. The minimum shaft diameter attainable with these instruments can limit the efficiency of some laparoscopic and minimally invasive procedures.

SUMMARY OF THE INVENTION

In its first aspect the invention provides a surgical fastening device. As used herein, the phrase *"surgical fastening device"* refers to any surgical device for inserting a surgical fastener into a body tissue and includes surgical staplers, and surgical joiners. As used herein, the phrase *"surgical fastener"* refers to any device configured to be inserted and anchored into a body tissue and includes, for

example, surgical staples, surgical pins, surgical anchors, surgical arrows and other types of fasteners used to join two tissues together, or to attach a synthetic device to a body tissue.

The surgical fastener of the invention is provided with an amount of a surgical filament. The fastener is configured to be inserted into a body cavity and to eject a surgical fastener so as to pin an end of a piece of the surgical filament to a body tissue in a first location in the cavity. The fastening device may then be moved to a second location in the cavity and a second fastener ejected from the device so as to pin another point on the filament to a body tissue at the second location in the cavity. The first and second locations of body tissue are thus connected to each other by a segment of the filament. The device is further configured to cut the filament so as to release the piece of the filament pinned at each of its ends to the first and second locations.

As used herein the term *"surgical filament"* refers to a filament having any cross sectional shape and made from a biocompatible material. The filament may have a rectangular cross section, such as a ribbon, band or strip, or may have a circular cross section, such as a cord, thread or wire. The filament may also be a hollow cylinder. The filament may be complete or may have perforations in it. The filament may also be a mesh or a net. The filament may be biodegradable or may be non-biodegradable.

The device of the invention may be used to attach one or more pieces of surgical filament into a body cavity in order to position an organ in the cavity, or to form a lattice of filaments to support a body tissue.

In its second aspect, the invention provides surgical fasteners for use in the surgical fastener of the invention.

In its third aspect, the invention provides surgical filaments for use in the surgical fastener of the invention.

Laparoscopic repair of inguinal hernia, for example, may be performed with the fastening device of the present invention using only one port. Abdominal wall defects can be closed using filaments attached to the tissue using

the proper tension, so as to prevent recurrence. The approach may be properitoneal, using a dissection balloon and creating a lattice-like structure from pieces of filament that closes the defect of the abdominal wall from inside using pieces of filament and attaching them to the tissue. Alternatively, hernia repair may be performed endoscopically through a small skin incision. The defect is closed from the exterior side and then a space is created with a balloon inserted above the posterior wall of the inguinal canal. The weakness of the posterior wall of the inguinal canal is closed with the filaments attached to the tissue. This procedure reproduces endoscopically the open Lichtenstein mesh hernia repair operation, and may be performed under local anesthesia.

Another type of surgery that can benefit from the device of the invention is urinary stress incontinence. Presently, open abdominal operation for treating urinary stress incontinence is performed through a large incision in the lower abdomen; the vaginal wall is sutured to the Cooper's ligaments situated on the pubic bone creating a hammock and support for the urethra and preventing stress incontinence. Alternatively, a vaginal incision and two small abdominal incisions are performed for inserting an elastic strip beneath the urethra and fasten it to the pelvic bone or other hard tissue such as the rectus sheath fascia, in order to support the urethra and stop uncontrolled urine.

In contrast to this, with the device of the invention, through one small vaginal incision, a sling or mesh strip can be inserted beneath the urethra, fixed with fasteners to the rectus sheath fascia tissue or bone without any additional incisions in the abdominal wall. Alternatively, the operation can be performed through a small abdominal incision. The extraperitoneal space before the urinary bladder is developed using a dissection balloon. The anterior vaginal wall is attached to the Cooper ligaments or to pubic bone. A filament is attached to the vaginal wall using one or more fasteners. Then the filament is tensioned and attached with one or more such fasteners to the cooper ligament or to the pubic bone. One or more such filaments are used on each side, reproducing the open Burch intervention, laparoscopically using only one or two ports.

The device of the invention may also be used, for minimal invasive repair of pelvic organ prolapse. Such interventions are performed presently through a large abdominal or vaginal incision.

Laparoscopic repair or pelvic organ prolapse may be performed with the present device using only one or two ports. The pelvic floor defects can be closed using filaments attached to the tissue using the proper tension, thus preventing recurrence.

Another application of the present invention is in the repair of gastroesophageal reflux. The posterior wall of the stomach is sutured to the anterior wall on the medial side of the esophagus creating a valve like structure and preventing gastroesophageal reflux (Nissen fundoplication). The operation with the device of the present invention can be performed by one operator using one or two ports. The instrument is introduced through the lesser omentum and the filament is attached to the posterior wall of the stomach that is then pulled toward the anterior wall of the stomach medial to the esophagus. Then the filament is properly tensioned and attached to the anterior wall reproducing Nissen fundoplication.

The present invention may also be used for performing laparoscopic anastomoses of various tubular organs such as intestines or blood vessels, or for closing defects in such structures. The present invention may also be used to close defects in tubular organs such as intestines, stomach, or urinary bladder by an endoscopic route (from inside). Such interventions may be performed using local anesthesia during gastroscopy, colonoscopy or cystoscopy. Endoscopic excision of large tumors in these organs may create defects which may be closed using filaments attached to one side of the defect with attachment means, then the filament and the tissue affixed to it is approximated to the other tissue (the other lip of the defect) and the filament is attached to this tissue under proper tension.

Another intervention that may be performed with this instrument is endoscopic repair of ureteropelvic obstruction that is the most frequent inborn

urinary tract anomaly. Currently, the gold standard for this operation is open pyeloplasty, that is performed under general anesthesia. Endoscopic repair of this anomaly can be performed by an antegrade or retrograde route, under local anesthesia. However, the results are inferior to the open repair since the defect created by incising the stricture is left open and can lead to restenosis.

Another endoscopic operation for the repair of ureteropelvic junction obstruction, endopyeloplasty, involves endoscopically incising the ureteropelvic junction longitudinally and closing the endoscopically in a transverse manner. With the prior art instruments, a suture is passed through the lips of the defect, the instrument is then removed and a knot is made extracorporeally and pushed down and then another instrument is introduced for cutting the suture thread. This sequence of maneuvers is performed for each suture 4 to 6 times. This procedure necessitates forming a large orifice in the flank and kidney for introducing the suturing instrument.

The fastening device of the invention may also be used in vaginal repair of stress incontinence. With the device of the invention, this procedure may be carried out under local anesthesia with reduced risk of injury to blood vessels, the urethra, urinary bladder bowels or nerves , which is known to occur during trans-abdominal or trans-vaginal surgery.

The fasteners of the present invention can be introduced under local anaesthesia through a small incision in the renal pelvis through the flank with ultrasound or fluoroscopic guidance. The strictured area can be incised longitudinally and the defect created may be closed transversally by attaching a biodegradable filament made, for example, from Vycril to one lip of the defect with anchors tensioning it, attaching the filament to the other lip, and closing the defect from inside. Since, the instrument may be as slender as 2 to 3 mm, the intervention may be performed expeditiously through a 5 mm orifice in the flank under local anesthesia.

Thus, in its first aspect, the invention provides a surgical fastening device for pinning a surgical filament to a body tissue, comprising:

(a) a grasping handle;

(b) a slender shaft extending from the grasping handle,

(c) a compartment configured to contain one or more surgical fasteners ;

(d) an activatable ejecting mechanism ejecting a surgical fastener from the compartment ; and

(e) a filament dispensing system configured to dispense surgical filament along the shaft so that a fastener grasps the filament when being ejected from the shaft.

In its second aspect, the invention provides a surgical fastener for use in the surgical fastening device of the invention.

In its third aspect, the invention provides a surgical filament for use in the surgical fastening device of the invention.

In its forth aspect, the invention provides a method for pinning a surgical filament to a first location of body tissue in a body cavity comprising introducing into the body cavity a surgical fastening device of the invention and ejecting a first surgical fastener from the shaft so as to pin a surgical filament to the first location.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a surgical fastener in accordance with one embodiment of the invention;

Fig. 2 shows a surgical fastener in accordance with a second embodiment of the invention;

Fig. 3 shows a surgical fastener in accordance with a third embodiment of the invention;

Fig. 4 shows a surgical fastener in accordance with a fourth embodiment of the invention;

Fig. 5 shows a surgical fastener in accordance with a fifth embodiment of the invention;

Fig. 6 shows a surgical fastening device in accordance with one embodiment of the invention;

Fig. 7 shows the distal end of the barrel of the device of Fig. 6;

Fig. 8 shows the ejecting mechanism of the device of Fig. 6;

Fig. 9 shows a surgical filament in accordance with one embodiment of the invention;

Fig. 10 shows a surgical filament in accordance with another embodiment of the invention;

Fig. 11 shows fastening a surgical filament at two locations in a body cavity;

Fig. 12 shows a surgical fastening device according to a second embodiment of the invention;

Fig. 13 shows the barrel of the device of Fig. 12;

Fig. 14 shows the ejection mechanism of the device of Fig. 12;

Fig. 15 shows the cutter of the device of Fig. 12;

Fig. 16 shows a surgical fastener according to a sixth embodiment of the invention;

Fig. 17 shows a surgical fastening device according to a third embodiment of the invention;

Fig. 18 shows a surgical filament according to a third embodiment of the invention;

Fig. 19 shows the barrel of the device of Fig. 17;

Fig. 20 shows the ejecting mechanism of the device of Fig. 17;

Fig. 21 shows a surgical fastener according to a seventh embodiment of the invention;

Fig. 22 shows a surgical fastening device according to a fourth embodiment of the invention;

Fig. 23 shows the central control rod of the device of Fig. 22;

Fig. 24 shows the distal end of the barrel of the device of Fig. 22;

Fig. 25 shows the inner sleeve of the device of Fig. 22; and

Fig. 26 shows repair of stress incontinence using a surgical fastening device of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows a fastener **20** in accordance with one embodiment of the invention. The fastener **20** is preferably made from a bio-compatible material such as stainless steel or Nitinol™. The fastener **20** has a prong **19** that terminates in a barbed tip **21**. The barbed tip **21** serves to anchor the fastener **20** in a body tissue when inserted into the tissue, as described below. The fastener **20** also has a tail portion **22** in the shape of a flat disc from which the prong **19** extends. As explained below, the fastener **20** is inserted into a body tissue by applying a force to a surface **24** of the disc **22** so as to impart a kinetic energy to the fastener **20** and cause the barbed tip **21** to enter the body tissue and become affixed in the tissue. The force applied to the surface **24** may arise, for example, from a compressed fluid or a compressed spring applied to the surface **24**.

Fig. 2 shows another embodiment **23** of the fastener of the invention in which a tip portion **28** of a prong **19** is provided with two or more pairs of spring-like barbs **25**. The barbs **25** are constrained in a compressed configuration shown in Fig. 2a during insertion of the tip portion **28** into a body tissue. The barbs **25** expand into the expanded configuration shown in Fig. 2b after insertion of the tip portion **28** into a body tissue. The fastener **23** preferably has 1 to 10 pairs of barbs **25**, and more preferably 2 to 4 pairs of barbs **25**.

The fastener **23** also has a tail portion **22** in the form of a disc to which a force is applied during insertion of the tip portion **28** into a body tissue, as explained above in reference to the embodiment of Fig. 1. The disc **22** is

provided with flexible tail members **26**. The tail members **26** are constrained in the compressed configuration shown in Fig. **2a** prior to insertion of the distal portion **28** into a body tissue, and expand into the expanded configuration shown in Fig. 2b in order to prevent the disc **22** from entering the tissue. The flexible members **26** can be covered with flexible sheet **27.**

Fig. 3 shows a fastener **40** in accordance with another embodiment of this aspect of the invention. The fastener **40** has a tail end **42** having a disc shape. The disc **42** is provided with two spring-like arcuate fins **48** extending from an edge **49** of the disc **42**. The fins **48** are initially constrained against the edge **49** when in a fastening device (not shown), and open into the configuration shown in Fig. 3 when released from the fastening device in order to prevent penetration of the tail end **42** from penetrating the body tissue.

Fig. 4 shows a fastener **50** in accordance with another embodiment of the invention. The fastener **50** comprises a helical coil **51**. A tip end **52** of the helical coil **51** is provided with a barb **53** for penetrating a body tissue and becoming anchored in the tissue. A tail end **54** of the helical coil is provided with a propeller **52**. When the fastener **50** is propelled towards a body tissue by applying a force to the tail end **54,** the propeller **54** causes the fastener **50** to rotate so as to allow the tip end to screw into the body tissue. The helical coil **51** may compress as it enters a tissue.

Fig. 5 shows a fastener **55** in accordance with another embodiment of the invention. The fastener **55** has a ring portion **56** from which extend two prongs **57**. The prongs **57** terminate in a barb **58**. The fastener **55** is formed from a biocompatible elastic or spring-like material such as stainless steel. The fastener **55** has a resting, or unconstrained configuration shown in Fig. 5a, in which the prongs **57** curve outwards from the ring portion **56**. As explained below, for insertion into a body tissue, the fastener **55** is constrained in a configuration shown in Fig. 5b in which the prongs **57** are straight. As the prongs **57** enter the body tissue, the prongs **57** revert to the unconstrained configuration shown in Fig. 5a. The ring portion 56 may originally have a circular cross section, as

shown in Fig. 5b, and may be deformed into an "I" shaped cross section shown in Fig. 5a in order to grasp a surgical filament, as described below. Alternatively, as shown in Fig. 5b, two diametrically opposed projections **60** may be cut in the ring portion **56.** The projections are constrained not to extend from the ring portion **56** when loaded in a fastening device, and spontaneously project inward, as shown in Fig. 5c when released from the fastening device in order to grasp a surgical filament.

Fig. 16 shows a fastener **200** in accordance with another embodiment of the invention. The fastener **200** has two barbed prongs **201** extending from a crown **202.** The fastener **200** has an unconstrained configuration shown in Fig. 16a in which the prongs **201** are directed towards each other. When the fastener is loaded into a fastening device, it is brought into a constrained state shown in Fig. 16b. When the fastener is subsequently ejected from the fastener device, it spontaneously assumes the unconstrained configuration shown in Fig. 16a in order to be anchored in a body tissue. In the constrained state shown in Fig. 16b, the prongs **201** are attached to the crown **202** at a curved regions **203,** so the prongs **201** and the crowns **202** do not lie in the same plane.

Fig. 21 shows a fastener **400** in accordance with another embodiment of the invention. The fastener **400** comprises a helical portion **402** that terminates in a barbed end **404.** The helical portion **402** extends from, and is firmly attached to a D-type fitting **406.** The edge of the fitting **406** thus consists of two cylindrical surfaces **407** and two planar surfaces **409.** A cap **408** mounted on the fitting **406** has a cross-shaped socket **410.** The socket **410** is configured to receive a complementary cross-shaped driving rod in order to rotate the fastener **402** so as to cause the fastener **400** to be screwed into a body tissue. The fitting **406** has two external screw threads **412,** that mates with internal screw threads in a fastening device as explained below.

Fig. 12 shows a surgical fastening device **100** in accordance with one embodiment of the invention. The fastening device **100** is used to insert the fastener **55** (Fig. 5) into a body tissue. The fastening device **100** includes a

cylindrical barrel **102** in which a plurality of fasteners **55** are stored, as described in detail below. The barrel **102** has a distal end **103** and a proximal end **105**.

The fastening device **100** has a grasping handle **101** from which the barrel **102** extends. The grasping handle **101** has a housing **104** enclosing an ejecting mechanism for ejecting a fastener **55** in the barrel **102** into a body tissue, as explained in detail below. The ejecting mechanism is activated by a user squeezing a trigger **106** towards a handle portion **107** of the housing **104**. The housing **104** also encloses a reel **108** of a surgical filament **109** that is used for joining body tissues together. A terminal segment of the filament **109** extends from the reel **108**, passing through the housing and barrel to the distal end of the barrel **102**. A portion of the reel **108** extends out of the housing **104** in order to allow a user to manually roll the reel so as to rewind filament back onto the reel. A locking pin **105a** allows a user to lock the reel **108** so as to prevent rotation of the reel **108.** The filament **109** may be a solid band, as shown in Fig. 9a. Alternatively, the filament may have holes along its length as shown in Fig. 9b. The filament **109** may also be a mesh, as shown in Fig. 10.

Fig. 11 depicts a surgical procedure in which a surgical fastening device, such as the fastening device **100**, is used to insert a fastener **55** at each of two tissue sites in side a body cavity. As shown in Fig. 11a, the shaft **102** of the device **100** is introduced into a body cavity **119** of a subject **115** through an incision at a first location **116** on the body surface. An endoscope **117** is introduced into the body cavity **119** through a second incision at a second location **118** on the body surface. The endoscope **117** illuminates the body chamber **119** containing the body tissue or tissues into which the fasteners **55** are to be inserted. The endoscope is part of an imaging system that displays on a display screen (not shown), an image of the cavity **119**, so as to allow a user **120** to observe the cavity **119** as the fasteners are inserted. The body cavity **119** may temporarily be expanded in order to enhance the maneuverability of the fastening device **100** and the endoscope **117** in the cavity **119.**

In Fig. 11a, the distal end **103** of the fastening device **100** has been brought to a first location **122** in the body cavity **119** where a first fastener is to be inserted. The user then squeezes the trigger **106** against the handle **107** so as to activate the fastener ejecting mechanism, and eject a fastener from the distal end of the shaft into the tissue at the first location **122.** As the fastener is ejected from the distal end of the shaft, the fastener firmly grasps the free end of the filament **109** at a location on the filament **109** adjacent to the distal end **103,** so that the free end of the filament becomes pinned to the tissue at the first location **122.**

Fig. 11b shows the filament after its free end has been pinned to body tissue at the first location **122** by a fastener **121.** As the user then moves the distal end of the shaft away from the first location **122,** filament **109** is fed from the reel **108** located in the grasping handle and through the shaft **102.** As the distal end **103** approaches a second location **124,** the reel **108** may be locked in order to prevent additional strip **109** from being released from the reel **108** by depressing the locking pin **105a** on the housing **104** (Fig. 12). As the distal end **103** is further moved towards the second location **124,** the first location **121** is pulled towards the second location **122** so as to displace a body organ, such as the body organ **123** towards the second location **124.** Before ejecting a fastener at the second location **122,** the user may manually rotate the reel **108** in order to retract an amount of the filament back onto the reel so that the filament is stretched taut between the first and second locations.

Fig. 11c shows the fastening device **100** after the distal end **103** has been brought to the second location **124** in the body cavity **119** where a second fastener is to be inserted into body tissue. As can be seen in Fig. 11c, the filament at this time extends from the first location **122** (where the strip is pinned to body tissue by the fastener **121)** to the second location **124.** The user then activates the fastener ejecting mechanism again to eject a second fastener at the second location. As the second fastener is ejected from the shaft, it grasps the filament in

the vicinity of the distal end of the shaft, so as to pin the strip at the second location.

The fastening device **100** includes a cutter, to be described below, located at the distal end of the shaft for cutting the filament **109.** Fig. 11d shows the strip **109** after having been cut by the cutter so as to release a segment of filament **109** pinned at its ends at the first and second locations **122** and **124** by the fasteners **121** and **125,** respectively. This process may be repeated as required during a single surgical procedure so as to deploy any number of filament pieces in the body cavity, so as to fix a body organ, such as the organ **123** in a desired position in the body cavity.

Fig. 13 shows an interior view of the shaft **102** of the fastening device **100.** The shaft **102** comprises three coaxial sleeves. A middle sleeve **115** is located between an outer sleeve **110** and an inner sleeve **111.** The inner sleeve **111** is separated from the middle sleeve **115** by an annular gap. A plurality of fasteners **55** in the constrained configuration shown in Fig. 5b are mounted on the inner sleeve **110** with the inner sleeve **110** passing through the ring portion **56** of the fasteners **55** (Fig. 5), so that the fasteners **55** are located in the annular gap between the inner and middle sleeves **111** and **115,** respectively. The inner sleeve is provided with a sequence of ratchet projections **112** that push the fasteners **55** in a distal direction when the inner sleeve **110** is pushed in the distal direction by an ejecting mechanism described below. The fasteners **55** may be provided with notches **59** in the ring region **56** (Fig. 5) to receive the tips of the projections **112** in order to prevent rotation of the fasteners **55** in the barrel during longitudinal displacement of the fasteners in the barrel. The middle sleeve **115** is also provided with spring-like projections **116** that prevent longitudinal movement of the fasteners **55** towards the proximal end **105** of the barrel when the inner sleeve **110** moves longitudinally towards the proximal end **105** of the barrel after a fastener has been ejected, as explained below.

The ejecting mechanism is configured to apply a force to the proximal end of the inner sleeve **110** so as to cause the entire stack to move one ratchet unit

towards the distal end **103** of the shaft **102**. As shown in Fig. 13, the distal most fastener **55a** in the stack is thus ejected from the distal end of the shaft **103**. At the distal end **103** of the shaft **102** is a fastener deformer **113**. As the distal most fastener **55** is ejected from the distal end of the shaft **102**, the fastener passes through the fastener deformer **113** causing the ring portion **56** to be deformed from the circular shape shown in Fig. 5b to the "I" shape shown in Fig. 5a. Deforming the circular portion **56** to the "I" shape causes the circular portion **56** to pinch and firmly grasp the free end of the filament **109**. The ejected fastener thus pulls the free end of the filament **109** as it is ejected, as shown in Fig. 13. As the end of the filament **109** is pulled by the ejected fastener, the spool **108** rotates so as to release more filament. Alternatively, the projections **59** (Fig. 5) may be used to grasp the filament **109.**

After the fastener **55** has been ejected from the shaft **102**, the prongs **57** spontaneously revert to their unconstrained configuration shown in Fig. 5a, so as to allow the fastener to become firmly attached at a specific location on a body tissue (the body tissue is not shown in Fig. 13). The free end of the filament **109** is thus also firmly attached to the same location on the tissue.

Fig. 14 shows an interior view of the grasping handle **107.** The interior sleeve **111** extends from the shaft **102** into the grasping handle **107** and terminates near the reel **108.** The fialment **109** extends from the reel **108** and is conducted through the interior sleeve **111** to the distal end **103** of the shaft **102.** The trigger **106** is spring biased in a released position shown in Fig. 14 by means of a restoring spring **128.** Squeezing the trigger **107** applies a force to the proximal end of the inner sleeve **110** in order to eject a fastener, as explained above. The reel **108** is provided with locking holes **108a** configured to receive the locking pin **105** (Fig. 12).

Fig. 15 shows the cutter located at the distal end **103** of the shaft **102** for cutting the filament **109.** Fig. 15a shows a segment of the filament **109** after being pinned to body tissue (body tissue not shown in Fig. 15) at two locations by a pair of fasteners **131** and **132.** The cutter consists of an "L" shaped notch

133 formed in the outer sleeve **110** extending from the distal end **103** of the shaft **102**. A lever **106a** (Figs. 12 and 14) is rotated about the barrel **102** in order to displace the outer sleeve **110** longitudinally towards the distal end of the barrel so that it extends beyond the deformer **113** as shown in Fig. 15b. The user then manipulates the distal end **103** so as to bring the filament **109** into the notch **133**, as shown in Fig. 15b. The lever **106a** is then released. Under the influence of a restoring spring **107a**, the lever **106.5** returns to its original position causing the outer sleeve **110** to move longitudinally towards the proximal end of the barrel. The filament **109** thus becomes sheared between a cutting edge **134** on the notch **133** and the deformer **113**, as shown in Fig. 15c.

Figs. 6, 7, and 8 show a fastening device **1** for inserting one or more fasteners in to a body tissue in accordance with another embodiment of the invention. The fastening device **1** may be used, for example, to insert any one of the fasteners **20**, **28**, **40**, or **52**. The fastening device **1** includes an insertion opening **62** configured to receive a magazine **63** containing plurality of fasteners **64**. Each fastener **64** is encased in a metal shell **69**. The shells **69** all have the same dimensions that are determined by the inner dimensions of the magazine **63** and a barrel **75**. A shell **69** can, however, accommodate fasteners of different sizes and shapes. In this way, the magazine **63** can be loaded with fasteners of different shapes, as required in any application.

The magazine **63** can preferably hold 5 to 40 shells **69**, and more preferably 10 to 20 shells **69**, each shell containing a fastener **65**. The shells **69** are fed one at a time, by a metal spring in the magazine **63** towards the barrel **75**. After ejecting a fastener **65**, the shell of the ejected fastener is ejected out of the barrel **75**, and may be collected separately in a bag or can.

The fastening device **1** also includes an ejecting mechanism to impart kinetic energy to a fastener so as to eject a fastener from the fastening device through the barrel **75**. The ejecting mechanism may be mechanical (i.e. by means of a spring). Alternatively, as shown in Fig. 8, the ejecting mechanism may be a pneumatic or hydraulic mechanism. Depression of a trigger **78** releases a

pneumatic valve **77** causing a compressed gas, such as compressed air, or a pressurized liquid fluid to be delivered from a source (not shown) into the barrel **75** of the fastening device **1** which imparts a kinetic energy to a fastener **65** in the barrel **75**. In this way, the fastener **65** is ejected from the fastening device **1.**

The barrel **75** of the fastening device **1** can be of a smaller diameter than the barrel diameter of conventional fastening instruments, due to the absence of a mechanical feeding mechanism or fastener deforming mechanism in the barrel **75.** For example, if the maximum external diameter of a fastener is 1 mm, then the external diameter of the barrel **75** can be as small as 2 mm.

The fastening device **1** also includes a cartridge **13** containing a reel of surgical filament **10.** If the filament **10** is attached to the barrel **75,** a cover tube (not shown) of up to **10** mm, and preferably up to **5** mm, outside diameter can contain both the barrel **75** and the filament **10.** The filament is pulled out along the barrel **75** before using the fastening device **1,** until the end **11** covers the distal end **6** of the barrel **5** as shown in Fig. 7. The filament **10** is provided with a series of holes. The filament passes through the trajectory of a fastener **20** as the fastener passes through the barrel so that the tip of the fastener passes through a hole **12** in the filament. The tail **22** of the fastener cannot pass through the hole so that the end of the filament becomes pinned to the tissue as the fastener penetrates the tissue. An amount of filament may then be released from the reel and a second fastener ejected. The filament thus becomes pinned at two locations in body tissue.

The filament is then cut by a cutting mechanism **40.** The fastening device **1** includes a cutting mechanism **40** to cut the filament **10** after affixing the filament at two locations to body tissue. As shown in Fig. 7, the cutting mechanism can be by means of mechanical scissors, a hot wire system or a hot RF tip element **41** that is isolated by a plate **42** from the barrel **5.** The electrical energy for the cutting element can be from an external source such as an electrical power supply or from an RF generator, or can be an internal device

battery. After cutting the detached piece of filament connects two tissue locations so as to provide support for a tissue or to hold two tissues together.

Fig. 17 shows a surgical fastening device **300** in accordance with another embodiment of the invention. The fastening device **300** is used to insert the fastener **200** (Fig. 16) into a body tissue. The fastening device **300** has a grasping handle **302** and a barrel **304**. The barrel **304** has a distal end **308** and a proximal end **309**. The grasping handle **302** has a housing **306** containing an ejecting mechanism for ejecting fasteners from the distal end **308** of the barrel **304**. The ejecting mechanism is activated by squeezing a trigger **310** towards a handle portion **312** of the grasping handle, as explained below. A fastener ejected from the distal end **308** pins a filament **314** to a body tissue

Fig. 18 shows the filament **314**. Initially, the filament **314** is a closed loop. The filament **314** has two rows of perforations **316** along its length. The filament **314** is loaded onto the fastening device **300** so that the filament **314** is loops around the proximal end **309** and the distal end **308** of the barrel **304**.

Figs. 19a to 19g show the distal end **308** of the barrel **304** in greater detail from several perspectives. The barrel **304** contains a stack of fasteners **200**. The fasteners **200** in the barrel **304** are in the constrained state shown in Fig. 16b.

At the distal end **308** of the barrel **304** is a first roller **318** and a pair of roller cutters **320**. As the filament **314** moves in the shaft **304**, the roller cutters **320** cut the filament **314** along the perforation **316**. A portion **322** of the filament **314** is thus released from distal end **308** having a series of notches **304** along each edge. Residual fibers **326** continue to the proximal end **304** of the shaft.

A central rod **330** extends through the length of the barrel **304**. A tongue **332** is hinged to the distal end of the rod **330** at an axis **334**. The distal edge **336** of the tongue **332** contacts the crown **202** (Fig. 16) of the distal most fastener **200a**. A flat spring **340** extends from the distal end of the rod **330** and maintains the distal edge **336** of the tongue **332** in contact with the crown **202**. The distal end of the barrel 304 is provided with a cutter 305 for cutting the filament 314.

The cutter may be, for example, a blade, an radiofrequency (RF) cutter, or a hot wire cutter.

Squeezing of the trigger **310** (Fig. 17) causes displacement of the rod **330** towards the distal end **308** of the barrel **304**. This movement of the rod **330**, in turn, causes the distal most fastener **200a** to be ejected from the distal end **308**. As the distal most fastener is ejected from the distal end, prongs **201** pass through notches **304** on the edges of the filament **314**, and then reverts to its unconstrained configuration (Fig. 16a), so as to be fixed in a body tissue. (The body tissue is not shown in Fig. 19).

Releasing the trigger **310** then causes the rod **330** to be displaced longitudinally towards the proximal end **309** of the barrel **304**. The stack of fasteners **200** is then displaced in the barrel **304** towards the distal end **308**. As the fastener **200b** slides by the tongue **332**, the tongue rotates slightly around the axis **334** against the flat spring **340**. When the crown **200** of the fastener **200b** has passed the distal edge **336** of the tongue **332**, the distal edge **336** rotates about the axis **334** under the influence of the spring **340**, so that the distal edge **336** is directly above, and in contact with the crown **200** of the fastener **200b**. Squeezing the trigger **310** would then cause the fastener **200b** to be ejected from the distal end **308**, as explained above.

Figs. 20a and 20b show the grasping handle **302** of the fastening device **300**, with the housing **306** removed for clarity. The central rod **330** extends into the grasping handle **302** at its proximal end. An annular ledge **342**, attached to the rod **330** supports a helical spring **346** surrounding a widened portion **348** of the rod **330**. Squeezing the trigger **310** against the handle portion **312** causes a first extension **354** of the trigger **310** to depress an annular ring **350** surrounding the rod **330** and mounted on the helical spring **346**. A stop **352** under the ledge **342** prevents the rod from being displaced longitudinally in the distal direction as the trigger is being squeezed. This causes the helical spring **346** to be compressed. As the trigger **310** continues to be squeezed, a second extension **356** of the trigger **310** contacts the stop **352** causing the stop **352** to rotate about

an axis **358** out from underneath the ledge **342** so as to allow the compressed spring **348** to rapidly revert to its resting state, so as to drive the rod **330** distally to eject a fastener as described above.

The grasping handle **302** also includes a knob **360** (Figs. 17, 20a and 20b) for maintaining a desired tension in the filament **314**. A knob **362** is used to lock the filament **314**

Fig. 22 shows a fastening device **420** in accordance with another embodiment of the invention. The fastening device **420** may be used to insert the fastener **400** into a body tissue. The fastening device **420** has a grasping handle **422** from which extends a barrel **424**. The barrel **424** has a distal end **428** and a proximal end **430** located inside the grasping handle. The grasping handle **422** has a housing **426** enclosing an ejecting mechanism for ejecting a fastener **400** from the distal end **428** of the barrel **424**. The ejecting mechanism is activated by squeezing a trigger **432** against a handle portion **434** of the grasping handle **422**. A fastener **400** ejected from the distal end **428** pins a strip **436** to a body tissue, as explained below.

A central rod **440** shown in greater detail in Fig. 23 extends from the grasping handle **422** into the barrel and terminates near the uppermost fastener **400a** in the barrel **424** to the distal end **428**. The rod **440** has a distal portion **442** and a proximal portion **444**. The distal portion **442** has a cross-shaped cross section and is configured to be received in the cross-shaped socket **410** of the fastener **400** (Fig. 21). The distal portion is located inside the barrel **424**. The proximal portion **444** is located in the grasping handle **422** and has a circular cross-section. The proximal portion **444** is provided with a helical screw thread **446**. The proximal portion is also provided with a helical groove **448** having a pitch that is greater than the pitch of the helical screw thread **446**. A hole **454** extends through the rod **440**.

The grasping handle **422** includes a selector **448**. The selector **448** has an integral lever **450** extending out of the housing **426**. The selector **448** can alternate between a first position shown in Fig. 22 in which the lever **450** is

raised and a second position (not shown) in which the lever **450** is lowered. The lever **450** is spring biased in the lowered position by means of a helical spring **452** surrounding the rod **440**.

The selector **448** has a control cavity **456** surrounding the rod **440.** Raising the lever **450** against the spring **452** brings the selector into the configuration shown in Fig. 22, in which inner screw threads **454** on a portion of the central cavity **445** engage the outer helical threads **446** on the proximal portion **444** of the rod **440** (Fig. 23). Squeezing the trigger **432** with the lever **450** held in its raised position causes the rod **440** to be displaced longitudinally towards the distal end **428**. The distal end of the rod is then received in the socket **410** of the proximal most fastener **400a** in the barrel **424**. The lever **450** is then released, so as to return to its lowered position under the influence of the spring **452**. In this configuration, the selector **448** is in its second configuration in which a second inner screw thread **458** engages the helical groove **448** on the proximal portion of the rod **440**. The trigger **432** is then released causing the rod **440** to rotate. Since the distal end of the rod **440** is inserted in the socket **410** of the uppermost fastener **400a** in the barrel, rotation of the rod **410** drives the rotation of the uppermost fastener **400a**.

As shown in Fig. 24, an inner sleeve **460** is located inside the barrel **424.** The inner sleeve surrounds the stack of fasteners **400**. The inner sleeve **460** has a cylindrical portion **462**. Two diametrically opposed cutting blades **464** extend from below the cylindrical portion **462** for cutting the filament **426**. Two diametrically opposed projections **466** extend above the cylindrical portion **462.** The projections **466** are planar and are parallel to each other and extend along the entire length of the barrel **424**. The stack of fasteners **400** is oriented between the projectors **466** with the planar surfaces **409** of the fasteners **400** parallel to the planar projectors **466** of the inner sleeve **460**. Thus, rotating of the uppermost fastener **400a** in the stack by the rod **440**, as explained above, causes the inner sleeve **460** to rotate, which in turn, causes all of the fasteners **400** in the stack to

rotate. Rotation of the lowermost fastener **400b** in the stack causes the helical portion **402** of the lowermost fastener **400b** to screw into a body tissue.

Fig. 25 shows the distal end **428** of the barrel in greater detail. An inner screw thread **470** on the inner surface of the barrel **424** engages the outer screw thread **412** on the fitting **407** of the lowermost fastener **400** (Fig. 21) in order to prevent the lower most fastener **400b** from inadvertently falling out from the distal end **428** of the barrel. The lowermost fastener **400b** can thus only be ejected from the distal end when rotated by the rod **440**, as explained above.

The filament **426** passes through the stack of fasteners **400** and extends beyond the distal end **428**. The filament has a circular cross-section and has bulges **468** periodically placed along its length. For example, a bulge **468** may be located every centimeter along the length of the filament **426**.

The filament **426** has a diameter that is less than the spacing of the turns of the helical portion **402** of the lowermost fastener **400b**. The bulges **468**, however, are too wide to pass between the turns of the helical portion **402** of the lowermost fasteners **400b**. Thus, as the lowermost fastener **400b** is ejected from the distal end **428** of the barrel, and screws into a body tissue, the filament enters in between the turns of the helical position **402** and thus becomes pinned to the body tissue. The presence of the bulges **468** then prevents the filament from slipping under the fastener **400b**. When the lever **450** and trigger **432** are then raised, the inner sleeve **460** extends beyond the distal end **428**. The cutting blades **464** then cut the filament as shown in Fig. 24.

Fig. 26 shows use of the fastening device of the invention in a method of vaginal repair of stress incontinence. The procedure is shown in an abodiminal view in Fig. 26a, and in a vaginal view in Fig. 26b. An incision 5 to 10 mm is made on the anterior vaginal wall over the urethra. A plane is then developed bilaterally between the vaginal wall and the urethopelvic ligament toward the attachment of this ligament to the arcuate ligament of the endopelvic fascia. The fasteing device of the invention is introduced through the incision towards the endopelvic fascia. A fastener **502** of the invention is then ejected from the

fastening device so as to pin an end of a filament **504** at a first location **500** on the endopelvic fascia on one side. The fastener is then removed through the vaginal incision, and is then reintroduced through the vaginal incision to the opposite endopelvic fascia and a second fastener **506.** is ejected from the fastening device so as to pin the filament at a second location **508** on the second side of the endopelvic fascia. The filament **504** is then cut by the fastener, so as to leave a piece of filament stretched between the two endopelvic fascia. The fastener is then removed through the vaginal incision.